

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

)
) MDL No. 1456
)

) CIVIL ACTION: 01-CV-12257-PBS
)

THIS DOCUMENT RELATES TO ALL
CLASS ACTIONS

) Judge Patti B. Saris
)
)
)

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF PROPOSED
CONSOLIDATED CLASS CERTIFICATION ORDER**

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I. INTRODUCTION

Pursuant to the Court's Certification Order ("Order") plaintiffs: (i) filed an amended complaint¹; (ii) filed a consolidated proposed class certification order ("CPO"); (iii) added class representatives for each class; and (iv) subsequently added Massachusetts based third-party payors ("TPPs") as class representatives.

As to Class 1 (Medicare Part B Co-Pay Class), plaintiffs have named as class representatives consumers who were prescribed a Part B covered drug from all Track 1 Defendants except Schering-Plough. By statute, the charge for a Part B drug must be based on AWP. Defendants' assertions that any co-payments or partial co-payments are not based upon AWP run contrary to the Court's rulings and to the statutory payment scheme recognized by the Court. Order at 15-16, 47.² Defendants' claims also run afoul of the evidence submitted by plaintiffs to the contrary, often consisting of Explanation of Benefits ("EOBs") from CMS,³ specifying that the class representative is responsible for 20% of the cost of a drug and of cancelled checks showing payment by the class representative. As to Schering-Plough, plaintiffs propose that a Class 3 individual representative can also serve as a Class 1 representative as their claims are typical – both will prove the exact same AWP manipulation. Finally, plaintiffs also propose as a further alternative, should it be necessary, that the Class 2 or 3 TPP representatives can also serve as Class 1 representatives because their claims are typical as well.

As to Class 2 (Third-Party Payor Medi-gap Supplemental Insurance Class), plaintiffs offer two alternatives. The Court held that plaintiffs had not grouped the proposed class on a basis allowing for certification. Order at 60. The TAMCC and the CPO track the Court's

¹ Third Amended Master Consolidated Complaint Amended to Comply With Court's Certification Order ("TAMCC").

² "Here, common factual issues predominate since a typical consumer by statute simply pays a percentage of AWP as a co-pay." Order at 47.

³ CMS is the federal agency that administers the Medicare Program.

concern and propose a Class 2 certification that (i) groups TPPs by the states that allow corporations to bring consumer claims (CPO pp. 4-5; TAMCC, ¶ 649, p. 274); and (ii) asserts compliance with the notice requirements raised in the Order. (Compare Order at 53-55 and 72 with TAMCC, ¶¶ 650-51.) Defendants have not quarreled with these groupings. Rather, the thrust of defendants' opposition to Class 2 is that a multi-state class is improper under the Order and should not be considered by the Court. Plaintiffs believe that the Order invited such grouping and expressly ruled that denial to a multi-state class was "without prejudice."⁴ Thus, plaintiffs ask the Court to certify a multi-state class for Class 2. As an alternative, should the court wish to try the Class 2 claims twice, once for the Massachusetts only TPP class, and then later for the properly grouped states, the Pipefitters Local 537 Trust Funds ("Pipefitters") is the proposed representative.⁵ With Pipefitters as a representative, the Court need not address defendants' only real opposition to Class 2, because plaintiffs have now proffered a Massachusetts-based TPP as a class representative. There are other Class 2 alternatives regarding representation outlined in Section III B-C below.

For Class 3 (Physician-Administered Class for Consumers and TPPs), plaintiffs again offer two alternatives. First, plaintiffs have responded to the Order by proposing a class consisting of states that allow consumer claims (TAMCC, ¶ 657) and those that allow corporate claims (TAMCC, ¶ 658), and have alleged compliance with any applicable state law notice provisions (TAMCC, ¶¶ 650-51). *See* Order at 53-55. Thus, plaintiffs again properly propose a multi-state class. Should the Court wish to certify a Massachusetts class only, plaintiffs propose

⁴ "Plaintiffs have not proposed feasible groupings of these statutes, as would be necessary to proceed. Accordingly, the motion to certify a nationwide class is denied without prejudice." Order at 60.

⁵ The Court granted the Pipefitters' motion to join as a representative plaintiff and plaintiffs have proffered documentation and witnesses establishing Pipefitters' AWP-based payments. In addition, BCBS of Massachusetts ("BCBS Mass") has served a pre-suit letter and either by agreement or by motion will seek to be a class representative. BCBS Mass has made Medi-gap payments for drugs from all of the Track 1 defendants.

that Pipefitters and BCBS Mass be the class representatives with the proposed consumer plaintiffs.⁶

The CPO also proposes that certification proceed on the injunctive aspects of this case under Fed. R. Civ. P. 23(b)(2). Defendants offered no meaningful opposition to a Rule 23(b)(2) class, and the Order did not preclude such a motion. *See* Order at 41 (“plaintiffs have not moved to certify under Fed. R. Civ. P. 23(b)(2).”).

Defendants’ sweeping attacks on the adequacy of all class representatives fails. An exemplar is the adequacy of plaintiff Leroy Townsend, a retired bank president and village councilman, who testified he fully understood his duties as a class representative.⁷ His testimony is typical of the other proposed representatives, and defendants’ attacks in this regard are offensive, overbroad, unsupported in fact and should be soundly rejected. Plaintiffs, many of whom are elderly cancer patients, searched their homes, offices and basements and produced thousands of pages and have sat for depositions. These plaintiffs have demonstrated more than sufficient knowledge of, and commitment to, the litigation to be deemed adequate under Fed. R. Civ. P. 23(a)(4).

⁶ Attached hereto as Exhibit A is a table outlining the proposed representatives under each formulation.

⁷ *See* Declaration of John Macoretta in Support of Plaintiffs’ Memorandum In Support of Proposed Consolidated Class Certification Order (“Macoretta Decl.”) at ¶ 2.

II. ALL OF PLAINTIFFS' CLASS 1 REPRESENTATIVES ARE ADEQUATE

A. Plaintiffs Have Proffered Six Individuals Who Are Adequate Representatives of the Medicare Part B Beneficiaries Class⁸

Defendants make the *ipse dixit* assertions that none of the proffered representatives for Class 1 are “adequate” or “typical” and none have “produced documents establishing that he or she made co-insurance payments under Medicare Part B based on AWP for a physician-administered drug manufactured by a Track 1 defendant.” Defs’ Opp. at 2-3. Yet, to make their case, defendants ignore the basic facts about these six admitted “Medicare beneficiaries” – *i.e.*, individuals covered by and subject to the rules of the federal Medicare Program⁹ – and they ignore relevant aspects of the extensive documentation that has been produced by plaintiffs to meet and exceed this Court’s directive.¹⁰

In brief, as set forth in detail in the TAMCC, the six proffered Class 1 Representatives have standing to pursue claims both in their own right and on behalf of a nationwide class of “similarly situated” Medicare beneficiaries, because they bought physician-administered drugs manufactured by the Track 1 Defendants and paid for them at AWP-based prices, as determined by the Medicare Program and its undisputed reimbursement regulations. Defendants have never contended that CMS did not follow the explicit Medicare regulations respecting its AWP-based

⁸ As set forth in detail in paragraphs 14 through 19 of the TAMCC, the following six (6) individuals – all of whom are Medicare beneficiaries who paid percentage co-pays of Medicare Part B drugs sold by Track 1 Defendants for the treatment of their respective cancers – have been proffered, along with their spouses and/or legal representatives, as adequate representatives of the listed Track 1 Defendant classes: (i) Reverend David Aaronson, for himself and his wife Susan Aaronson [BMS, GSK, J&J]; (ii) James Shepley, for himself and his wife Theresa Shepley [AstraZeneca, J&J]; (iii) Robert Howe, for himself and his wife Joyce Howe [AstraZeneca, GSK]; (iv) Larry Young, as administrator of the estate of Patricia Young [BMS, J&J]; (v) Roger Clark, as administrator of the estate of his father David E. Clark [GSK, J&J]; and (vi) Leroy Townsend, for himself and his wife Margaret Townsend [AstraZeneca] (collectively referred to hereinafter as “the Class 1 Representatives”). Although the TAMCC does not presently reflect the addition of certain spouses/legal representatives of the Medicare beneficiaries, this has proven necessary because of the unfortunate declining health condition of these many infirm clients and will be accomplished as soon as practicable by amendment of the TAMCC to ensure that a consistent approach is taken and continual representation of Class 1 is maintained.

⁹ Defendants concede that the six Class 1 Representatives “are actually Medicare Part B beneficiaries.” Defs’ Opp. at 2.

¹⁰ The Order directed plaintiffs to “disclose the documents demonstrating that the proposed class representatives made co-insurance payments (at least in part) under Medicare Part B based on AWP.” Order at 43-44.

reimbursement formulae for covered drugs. To the contrary, defendants conceded this very point when pressed by the Court at the class certification hearing last winter.¹¹ Moreover, this Court consistently has held that these same Medicare regulations unambiguously provide for reimbursement of covered drugs at prices based on AWP.¹² Consequently, it is beyond peradventure that when Medicare beneficiaries pay all or part of their percentage co-insurance obligations required by the Medicare program,¹³ those payments are based on AWP. The fact that some of the Class 1 Representatives had partial insurance to cover some, but not all, of their percentage co-pay obligations under Medicare does not undermine their rights to prosecute defendants' unlawful marketing and sale practices under the consumer fraud laws of this country or to recover damages for the same.¹⁴ The six Class 1 Representatives clearly "meet the Court's test for membership in Class 1." Defs' Opp. at 9.

¹¹ At the February 10, 2005 hearing, this Honorable Court inquired directly of defense counsel as to whether defendants were contending that Medicare reimbursed upon any basis other than AWP, to which counsel responded unequivocally, "No, your Honor." See Transcript from hearing held on February 10, 2005 ("Class Cert Hrg Tr."), attached hereto as Exhibit B, at p. 41. Defendants also conceded in their briefing on class certification that AWP is the benchmark upon which the government bases its reimbursement for prescription drugs under Medicare Part B. See Track 1 Defendants' Memorandum in Opposition to Class Certification, filed October 25, 2004 ("Track 1 Defs' 2004 Opp. Mem."), at 16. To the extent Defendants are seeking now to retrench from these judicial admissions in their recent filing, they should be estopped.

¹² See, e.g., *Montana v. Abbott Labs.*, 266 F. Supp. 2d 250, 252 (D. Mass. 2003) ("In setting reimbursement rates, the Medicare program uses the AWP's generated by the pharmaceutical industry."); Certification Order at 14 ("AWP was the basis for drug reimbursement under Medicare Part B for most of the proposed class period.").

¹³ Order at 16 ("Medicare pays 80% of the allowed amount of a covered drug, and the beneficiary is responsible for paying the other 20%. 42 U.S.C. § 13951(a)(1)(S).").

¹⁴ Defendants appear to be claiming that, simply because *some* of these consumer Medicare beneficiaries had collateral sources of payment for *part* of their drug cancer therapies, there can be "no harm, no foul" from their unlawful marketing and sales activities. However, the law does not permit defendants to cite "collateral source" payments received by an injured party as a credit against a tortfeasor's liability, even if the payments cover all or part of the harm for which the tortfeasor is liable. See generally RESTATEMENT (SECOND) OF TORTS § 920A(2) (2005). Indeed, the collateral source rule is specifically intended to apply to insurance policy benefits, gratuitous payments, and "social legislation benefits" (including Medicare payments). *Id.* at Comment c (1), (4); see also *Clausen v. SEA-3, Inc.*, 21 F.3d 1181, 1192 (1st Cir. 1994) (affirming trial court ruling preventing defendant from cross-examining plaintiff about Social Security Benefits); *Hawkinson v. Geyer*, 352 N.W.2d 784, 789 (Minn. Ct. App. 1984) (defendant not entitled to offset for Medicare benefits paid to plaintiff); *Ciminski v. SCI Corp.*, 585 P.2d 1182, 1183-84 (Wash. 1978) (same); *Womack v. Travelers Ins. Co.*, 258 So.2d 562, 568 (La. App. 1972) (same). Accordingly, defendants should be not permitted to undermine the standing of the Class 1 Representatives to prosecute this case on grounds that some were compensated in part for their inflated, AWP-based payments by Medicare and supplemental insurance.

B. The Class 1 Representatives Are All Members of the Class of Medicare Beneficiaries

Consistent with their opposition's overall approach, defendants ignore the myriad documents produced by plaintiffs showing the membership of all six representatives in Class 1. *See generally* Declaration of Donald E. Haviland, Jr. and Macoretta Declaration In Support of Plaintiffs' Proposed Consolidation Order ("Haviland Decl.") (setting forth the detailed history of each of the Class 1 Representatives' drug purchases and payments). Each Class 1 Representative made percentage co-insurance payments toward all or a portion of their 20% co-payment obligations under Medicare Part B.¹⁵

The Haviland and Macoretta Declarations debunk each of defendants' attacks on the proposed Medicare Part B co-pay plaintiffs by establishing the Medicare status of the plaintiff and the identity of the Part B covered drug purchased by the plaintiff, and reviewing the medical bill, the EOB from CMS and, in some instances, checks that plainly remit some balance of the co-pay bill after Medicare paid its share. *See, e.g.*, Haviland Decl., ¶¶ 17-29 (regarding Aaronson); ¶ 36 (discussing checks and bills of the Shepley's payments for Procrit and Zoladex); ¶¶ 40-42, 43 n.21 (regarding payment for drugs manufactured by AstraZeneca and GSK and paid for by Mr. Howe); ¶ 47 (describing the Youngs making payments for Remicade and attaching their checks/credit card receipt); ¶¶ 50-52 (describing payments by Clark); and Macoretta Decl. ¶¶ 3-7 (describing payments by Townsend). Such evidence puts to rest defendants' claims that plaintiffs failed to produce a single document evidencing a payment based upon AWP.¹⁶

¹⁵ Instead of addressing the actual documents reflecting the actual situations of these six individuals, defendants make sweeping claims about other Medicare beneficiaries, such as "[n]ot all [of them] actually pay their 20% co-payments..." and that some portion of them [though not all and certainly not the Class 1 Representatives] allegedly had gap insurance that paid the entirety of the consumers' drug co-payment obligations. Defs' Opp. at 3-4.

¹⁶ Repeatedly, defendants charge plaintiffs' counsel with "flatly refus(ing)" to produce documents reflecting drug payments, indeed going so far as to accuse plaintiffs of "stonewalling." Defs' Opp. at 4. Nothing could be further from the truth. As detailed in both the Haviland Decl., ¶¶ 17-56, and Declaration of Jennifer Fountain Connolly In Support of Plaintiffs' Memorandum in Support of Proposed Consolidated Class Certification Order ("Connolly Decl."), ¶¶ 25-70, plaintiffs timely produced the materials in their possession, custody and control. But

C. The Class 3 Individual Representatives are Also Adequate Representatives for Class 1

Should the Court find that any of the proposed Class 1 co-pay plaintiffs are inadequate, or in the case of Schering an individual co-pay representative is missing, the answer is not to decertify. Rather, the Court should find that other, existing individual class representatives would be typical and adequate.

The claims of an individual Class 3 representative are typical of the claims of Class 1 Medicare co-payers under Rule 23(a)(3)'s straightforward test. Typicality is met when the claims of the representative plaintiffs (i) arise from the same course of conduct that gives rise to the claims of the other class members, and (ii) are based on similar legal theories. *Priest v. Zayre Corp.*, 118 F.R.D. 552, 553 (D. Mass. 1988) (quoting *In re Elscint, Ltd. Sec. Litig.*, Civ. No. 85-2622-K, slip op. at 18 (D. Mass. June 22, 1987)); *Randle v. SpecTran*, 129 F.R.D. 386, 391 (D. Mass. 1988); *Fraser v. Major League Soccer, L.L.C.*, 180 F.R.D. 178, 181 (D. Mass. 1998); *Burstein v. Applied Extrusion Techs.*, 153 F.R.D. 488, 491 (D. Mass. 1994); *see also* 1 A. Conte and H. Newberg, *NEWBERG ON CLASS ACTIONS* § 3.13 (4th ed. 2002) (the typicality requirement is usually met "when it is alleged that the same unlawful conduct was directed at or affected both the named Plaintiffs and the class sought to be represented"). As the court in *M. Berenson* noted, "[t]ypicality refers to the nature of the claim of the class representatives, and not to the specific facts from which the claim arose or relief is sought." *M. Berenson Co. v. Faneuil Hall Marketplace, Inc.*, 100 F.R.D. 468, 470 (D. Mass. 1984) (citation omitted); *see also Duhaime v. John Hancock Mut. Life Ins. Co.*, 177 F.R.D. 54, 63 (D. Mass. 1997) (finding

rather than rest on the documents within their control, which is all that this Court required in its Order, plaintiffs affirmatively went out and sought documents from other sources including the medical providers, the insurers and the federal government. Haviland Decl. at ¶¶ 5-7, 11-13, Ex. A. These efforts produced inconsistent results, depending on the plaintiff, but represent the best that could be accomplished under the circumstances of the Court-ordered deadlines.

typicality in case involving deceptive scheme to induce plaintiffs to purchase life insurance policies even though plaintiffs were deceived by different members of the sales force in slightly different ways, because, as a general matter, plaintiffs were subjected to the same deceptive sales techniques).

For purposes of typicality and adequacy, there is no substantive difference between a private insured's inflated co-pay claim in Class 3 and a Medicare Part B beneficiary's inflated co-pay claim in Class 1:

- Both individuals made co-pays on the basis of reimbursement formulas incorporating AWP.
- Both individuals had no role in establishing those reimbursement formulas.
- Both individuals suffered the same damage: paying inflated co-pays as a direct and proximate result of Defendants' AWP scheme.
- Both individuals pursue the same legal claims against Defendants, *i.e.*, violations of state consumer protection acts.
- There are no "knowledge" issues affecting the claim of either individual.

Thus, it is clear that the claims of individuals in Class 3 arise from the same course of conduct that gives rise to the claims of the members of Class 1, and the claims are based on similar – if not identical – legal theories. *Priest*, 118 F.R.D. at 553. Those representatives are typical and adequate and should be Class 1 representatives.

D. The Class 3 TPP Representatives Are Also Adequate Representatives for Class 1

If the Court has any fact issues with Class 3 individual representatives that cloud the typicality of their claims to represent their own Class or Class 1, the proposed Class 3 TPPs are also adequate Class 1 representatives. This is not a request to have the Court reconsider the prior decision that a Medi-Gap insurer's claims were not typical of the claims of individual Medicare beneficiaries. Notably, the non-Medi-Gap TPPs are different from Medi-Gap insurers *because*

the Court itself has already said so: “Unlike in the Medicare Part B context, here the TPP serves as the intermediary for its plan beneficiaries in negotiating with providers over reimbursement rates, and no conflict is immediately apparent.” Order at 62 n.24.

Case law supports a finding that Class 3 TPP representatives have claims that are typical of the Class 1 members. As per *Priest*, 118 F.R.D. at 553, the claims of the two classes arise from the same course of conduct and are based on similar legal theories:

- Both classes made co-pays on the basis of reimbursement formulas incorporating AWP.
- Both classes suffered the same damage: paying inflated co-pays as a direct and proximate result of Defendants’ AWP scheme.
- Both classes pursue the same legal claims against Defendants, *i.e.*, violations of state consumer protection acts.

See also General Tel. Co. v. Falcon, 457 U.S. 147, 159 n.15 (1982) (proof that an employer operated under a general policy of discrimination may justify a class including **both** applicants and current employees if the discrimination manifested itself in hiring and promotion practices in the same general fashion); *Almenares v. Wyman*, 453 F.2d 1075, 1080 n.7 (2d Cir. 1971) (AFDC recipients had claims typical of the claims of Aid to the Aged, Blind and Disabled recipients because the same hearing regulations applied equally to both programs); *Ortiz v. Eichler*, 616 F. Supp. 1046, 1056-57 (D. Del. 1985) (benefit recipients were proper representatives of both recipients of, and applicants for, benefits because the hearing procedures that allegedly harmed recipients are the same procedures that allegedly harmed applicants; the claims are coextensive).

In sum, Class 3 TPP representatives have the same incentive to pursue their claims as Medicare Part B beneficiaries who made inflated co-pays. The Class 3 representatives, in pursuing their own self-interest in the litigation, will also necessarily be advancing the interests

of the members of Class 1 because those interests coalesce. This is the essence of Rule 23(a)(3)'s typicality test.

E. UFCW Can Also Serve as the Class 1 Representative

Alternatively, UFCW which has made co-pays for drugs manufactured by all of the Track 1 Defendants, could serve as a Class 1 representative. Because UFCW made inflated AWP-based payments for subject drugs, UFCW's claims arise from the same course of conduct that gives rise to the claims of the Class 1 members. UFCW also pursues the same legal claims as do the members of Class 1. Accordingly, UFCW's claims are typical of the claims of Medicare Part B beneficiaries.

The Court has expressed concern that a TPP serving as a Class 1 representative could have a conflict in evaluating possible *settlements* for Medicare Part B beneficiaries, but such a concern should not preclude finding that UFCW would be an adequate Class 1 representative. First, at this time any such conflict is purely hypothetical, and speculative conflicts should be disregarded at the class certification stage. *In re Visa Check / MasterMoney Antitrust Litig.*, 280 F.3d 124, 145 (2d Cir. 2001). The conflict must be "fundamental" to defeat certification, and speculative conflicts are not fundamental. *Id.*; *In re Transkaryotic Therapies, Inc. Sec. Litig.*, 2005 U.S. Dist. Lexis 29656, at *15-16 (D. Mass. Nov. 28, 2005). Furthermore, there are procedural protections short of failing to certify Class 1 that can be enacted to alleviate the Court's concern about potential conflicts at a later date. One example is the formation of an Allocation Committee at the time of settlement discussions like those used in *In re Relafen Antitrust Litig.*, 231 F.R.D. 52 (D. Mass. 2005), and *In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508, 515, (E.D. Mich. 2003), where separate blocks of attorneys were appointed to represent the interests of TPPs and individual consumers, respectively, for purposes of dividing up the proposed settlement amount. The *Relafen* court found that such structural protections

overcame any objections of intra-class conflicts. 231 F.R.D. at 69-70;¹⁷ *see also In re Lupron® Mktg. & Sales Practices Litig.*, 228 F.R.D. 75, 49-50 (D. Mass. 2005) (approving settlement in which TPPs and consumers participated jointly and noting that no objector complained of the disparity in the benefits negotiated on behalf of consumer-purchasers and TPPs); *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 260 (D. Del. 2002) (approving settlement and recognizing that the plan of allocation was agreed to by both consumer and TPP class representatives), *aff'd*, 391 F.3d 516 (3d Cir. 2004).

Plaintiffs suggest that appointing UFCW as a Class 1 representative, thereby assuring a representative who has made a Part B co-pay for all of the Track 1 Defendants, in addition to the individual plaintiffs, is a preferable result than not certifying claims against some of the defendants.

III. PLAINTIFFS' PROPOSED CLASS 2 REPRESENTATIVES ARE ADEQUATE, AND THE CLASS SHOULD BE CERTIFIED

A. Plaintiffs' Proposed Order Certifying a Class Under the Laws of Multiple States Complies With This Court's Order Certifying the Class

Defendants claim that plaintiffs' proposed multi-state class for Class 2 is not permitted under the Order. The Court found that plaintiffs had not met their burden of proving that grouping of state law was feasible (Order at 53) and in particular noted that plaintiffs had not responded to grouping the Class to omit states that did not permit consumers to assert claims or had notice requirements. Order at 55. Plaintiffs have in the TAMCC grouped the claims by states that allow consumer claims to be brought by corporations and have alleged compliance with any applicable state law notice provisions. *See TAMCC*, ¶¶ 649-51. The CPO reflects this

¹⁷ The court also cited to the peripheral participation in the negotiations of the consumer advocate group Prescription Access Litigation Project ("PAL"). *Id.* at 70 & n.14. PAL's attorneys are also involved in the instant case and would most certainly be involved in any allocation discussions that may occur in association with future settlements.

grouping by proposing certification only in the states where TPP claims are allowed. Defendants offered no substantive opposition to this grouping.

Trying this claim as a multi-state class will be more efficient than trying the Massachusetts class only and then retrying the class for multiple states. Further, multi-state certification will promote resolution; otherwise, defendants have a “wait and see” attitude toward settlement, *i.e.*, let’s not settle until certification is resolved, which could be far down the road.

B. There Are Multiple Representatives for Class 2

1. UFCW, Pirelli and Sheet Metal Workers have claims typical of those of the Class 2 members

The Court has already determined that UFCW is an adequate representative for Class 2 (Medi-Gap Payors). Order at 58-59. UFCW made co-payments for a Part B covered drug manufactured by each Track 1 Defendant. Thus, if the Court accepts the multi-state grouping, to which defendants offer no substantive objection, typicality has been established.¹⁸

If the Court should certify only a Massachusetts class, defendants claim that UFCW, Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust (“Pirelli”), and Sheet Metal Workers National Health Fund (“Sheet Metals”), cannot be class representatives because they are not covering lives in Massachusetts. Defendants point to no reason why the proposed TPPs’ claims are not typical of any Massachusetts-based TPP, nor any reason why these TPPs would not adequately pursue such claims. Defendants raised this “Massachusetts issue” in their petition to the First Circuit, which was denied. In any event, if the Court is concerned with the absence of a Massachusetts TPP for Class 2, the answer is not to decertify, but instead is to either accept the multi-state class proposed, to allow UFCW to proceed as the class representative since it has

¹⁸ The adequacy of Pirelli and Sheet Metal Workers is addressed in the Connolly Decl., ¶¶ 19-23.

the proper incentive to do so, to certify a statewide class based on the law of Illinois¹⁹ or Tennessee,²⁰ or permit BCBS Mass to step forward.

2. UFCW, Pirelli and Sheets Metal Workers are adequate Class 2 representatives

The discovery that plaintiffs have produced on behalf of their Class 2 representatives, as well as this Court's previous rulings regarding UFCW, establishes that all of plaintiffs' proposed Class 2 representatives are adequate. Namely, all three representatives – UFCW, Pirelli and Sheet Metal Workers – made 20% co-payments for the Medicaid Part B drugs at issue in this litigation. As this Court has already held, reimbursement under Medicare is, by statute, based on AWP. *See* Order at 14 (“AWP was the basis for drug reimbursement under Medicare Part B for most of the proposed class period.”).

The documents Pirelli has produced establish that Pirelli made payments for drugs manufactured by three of the Track 1 Defendants – BMS, AstraZeneca, and J&J. Sheet Metal Workers made payments for drugs manufactured by four of the five Track 1 Defendants – BMS, AstraZeneca and J&J.²¹ *See* Connolly Decl., ¶ 22.

Defendants claim that the records produced by Pirelli and Sheet Metal Workers do not reflect the manufacturer who made the multi-source drugs for which Pirelli and Sheet Metal Workers made co-payments. Plaintiffs have asked defendants several times to produce information showing whether they sold their drugs to the providers reflected in the documents produced by Class 1, 2 and 3 representatives including Pirelli and Sheet Metal Workers.

¹⁹ Illinois is UFCW's principal place of business.

²⁰ Tennessee is the principal place of business of the other two proposed Class 2 representatives.

²¹ Like Pirelli, Sheet Metal Workers' records are, for the most part, unavailable in electronic form. Therefore, Sheet Metal Workers' document review is ongoing. It is extremely likely that Sheet Metal Workers will locate documents reflecting that it made co-payments for drugs manufactured by Schering-Plough as well. *See* Connolly Decl., ¶ 22. Plaintiffs will update this information prior to the hearing.

Defendants have refused to comply with this request.²² If defendants had produced those documents, it would be easy to confirm the identity of the manufacturer. Therefore, defendants cannot complain that Pirelli and Sheet Metals have not satisfied their burden of producing responsive documents, and the Court should presume at this point that the Track 1 Defendants are the manufacturers.

Defendants also claim that they were unable to ask Pirelli about the documents it produced in because plaintiffs purportedly did not make Pirelli available for a deposition within the time period permitted by the Court. *See* Defs' Opp. at 16 n.22. However, as set forth in further detail in the attached Connolly Declaration, plaintiffs did make Pirelli available for a deposition, and, when those dates did not work for defendants, defendants refused to take Pirelli's deposition on November 23rd, a mere six days after this Court's deadline for class representative discovery. *See* Connolly Decl., ¶ 21.²³

3. The Court can appoint Massachusetts-based Pipefitters or BCBS Mass as the Class 2 representative

Alternatively, if the Court wishes to stay with a Massachusetts only class and deems it necessary to have a Massachusetts-based TPP as the class representative, then the Pipefitters is adequate, and its claim are typical. Pipefitters did not make Part B co-payments, rather it paid for physician-administered drugs not covered by Part B.²⁴ Nonetheless, its interest in proving

²² *See, e.g.*, Letter to D. Scott Wise from Steve W. Berman dated October 26, 2005, Ex. 7 to Dove Decl.; and Haviland Decl., Ex. E, a November 9, 2005 letter again requesting this information.

²³ Defendants' insincere efforts at attempting to negotiate a deposition date for Pirelli makes their cry that the thirty days permitted by the Court is too short to take "adequate discovery" from Pirelli ring hollow. *See* Defs' Opp. at 17 n.23.

²⁴ *See* Declaration of Charles Hannaford.

AWP inflation is identical to that of any Massachusetts-based TPP that made co-payments for Part B covered drugs. Pipefitters would be an adequate Class 2 representative.²⁵

IV. PLAINTIFFS' PROPOSED CLASS 3 REPRESENTATIVES ARE ADEQUATE, AND A MULTI-STATE CLASS SHOULD BE CERTIFIED

A. Plaintiffs Propose a Multi-State Class Grouped By States that Allow Consumer and TPP Claims

As they did with respect to Class 2, defendants argue that the Court did not permit the filing of a complaint and/or a proposed order that seeks a multi-state class. As noted above, the Order did not prohibit such a filing, and plaintiffs have grouped the Class 3 claim by states that allow consumer and TPP claims. *See* TAMCC, ¶ 657, p. 279 (consumer claims) and TAMCC, ¶ 658, p. 283 (TPP claims). Defendants offer no substantive opposition to these groupings.

B. An Adequate Representative Exists for the Massachusetts Class If this is the Path the Court Chooses to Follow

Should the Court decline to certify Class 3 on a multi-state basis, plaintiffs have Massachusetts-based TPPs that can serve as the class representative. The Court has granted plaintiffs' motion to add Pipefitters Local 537 Trust Fund ("Pipefitters") as a class representative. Pipefitters is based in Massachusetts and paid for drugs manufactured by each of the Track 1 Defendants, except Schering-Plough.

Further, once the 30 day pre-suit period expires, BCBS Mass will assert a claim as a class representative, and it paid for drugs manufactured by all Track 1 Defendants.

Pipefitters and BCBS Mass thus have typical claims, and defendants' arguments regarding the lack of a Massachusetts representative are now moot.

²⁵ Pipefitters did not pay for drugs manufactured by Schering-Plough. However, by the time of the January 19, 2005 hearing, information on BCBS Mass will be available, and BCBS Mass has made Medi-gap payments for all defendants.

C. Discovery Has Established That Plaintiffs' Consumer Class 3 Representatives Are Adequate

Discovery produced by the consumer representatives proposed for the multi-state Class 3 has established that those representatives are adequate because they paid out-of-pocket for drugs at issue in this litigation whose payment was based on AWP. For the UFCW Class 3 individual representatives, plaintiffs began an exhaustive investigation and document production nearly immediately after this Court's issuance of the Certification Order. This process is described in detail in the attached Connolly Decl. *See id.* ¶¶ 3-12. Specifically, in addition to gathering medical records and financial records from third parties, for each proposed individual class representative, plaintiffs produced a printout from UFCW's database showing, *inter alia*, (i) the drug(s) administered each proposed representative; (ii) the amount UFCW paid; (iii) whether the beneficiary had other insurance; and (iv) the amount the proposed representative paid.²⁶ In addition, plaintiffs produced an affidavit from each representative specifying which AWPIDs they were administered, that they did not have supplemental insurance, and affirmatively stating that they had authorized plaintiffs' counsel to do further investigation.²⁷ The production on behalf of the non-UFCW Class 3 consumer representatives was similarly exhaustive. Haviland Decl. ¶¶ 2-13, Ex. A.

Despite plaintiffs' extensive production of records, defendants still claim that the discovery on these proposed representatives has shown them to be inadequate. First, Defendants claim that plaintiffs have not produced documents sufficient to identify the manufacturer of the drugs administered to the proposed representative. As defendants are aware – but have not

²⁶ Throughout their Opposition, Defendants refer to these spreadsheets as created by plaintiffs' counsel. They were not. Rather, plaintiffs' counsel simply sorted a database produced by UFCW to avoid having to produce over 1,000 pages of data that plaintiffs would have to redact to comply with HIPAA and that Defendants would have to sort themselves. *See* Connolly Decl., ¶ 24 (describing same).

²⁷ *See* Connolly Decl., Ex. 3 (Affidavits of Bonne Barnewolf; Cheryl Barreca; Anna Choice; Joyce Dison; Tracy Garcia; Gerald Miller; Joseph Miller; Donna Kendall; Sandra Leef; Constance Nelson; Andre Palencia; Regina Shoemaker; Scott Tell; Pauline Vernick; and Susan Wessels).

informed this Court – plaintiffs are in the process of obtaining this information and, in several cases, plaintiffs have produced this information to defendants. *See* Connolly Decl., ¶ 10. And defendants have refused to produce documents identifying providers to whom they sold, which would provide an easy answer to this question. Haviland Decl., ¶ 9-10. Second, defendants claim that certain proposed representatives have not produced evidence that they paid for the AWPIDs administered them. This is false. *See* Haviland Decl., ¶¶ 53, describing payments by Mrs. Hopkins and attaching payment records; ¶ 56 attaching payment records for Mr. Thompson. Proposed representatives Mary Cauble, Regina Shoemaker, Joseph Miller, and Scott Tell – the remaining proposed representatives specifically mentioned by defendants – have all produced documents reflecting their payments for AWPIDS. *See* Connolly Decl., ¶¶ 32-33, 53, 60-61, 63-64. And no issue is raised over payments made by other proposed Class 3 representatives. *See, e.g.,* Connolly Decl., ¶ 25 (Barnewolt); ¶ 38 (Choice); and ¶ 57 (Palencia).

These consumer Class 3 representatives have thus satisfied the requirements of the Order.

V. PLAINTIFFS NEED ONLY PROFFER A PURCHASER FOR ONE DRUG PER DEFENDANT

Defendants imply throughout their brief that plaintiffs must proffer a class representative who paid for each of the drugs manufactured by each Track 1 Defendant. This Court never made such a holding; nor would it make sense to do so: A plaintiff can establish standing merely by having made a co-payment for drugs made by one of the Track 1 Defendants. To establish standing, a named plaintiff must show he or she has been injured by a defendant's conduct. *See O'Shea v. Littleton*, 414 U.S. 488, 494 (1974). Having established injury from the purchase of one inflated drug from a defendant, no case holds that a plaintiff does not have standing to represent class members who suffer the same injury from the same scheme, albeit a different drug. This is not a situation where a plaintiff lacking any injury seeks to “back door” standing

by the class device. There are 30 drugs at issue in Track 1. There are three classes. If plaintiffs must have a purchaser for each drug and defendant as opposed to one per defendant, as many as 90 class representatives could be needed just for Track 1 depending on how many multiple drug purchasers there would be. This number would be much higher for Track 2 given the larger number of drugs and defendants joined in Track 2.

Furthermore, if a plaintiff was administered one drug manufactured by a defendant, its claims are typical *vis-à-vis* all drugs targeted for that particular defendant because (i) the AWP inflation scheme was implemented on a common basis for all drugs targeted, and (ii) the same legal claims apply for all targeted drugs. Again the test for typicality is not that all claims be identical, but that they arise from the same course of conduct. Order at 37.

VI. CERTIFICATION OF A (B)(2) CLASS IS APPROPRIATE

The Court found that the Association plaintiffs lack standing for claims seeking monetary relief and that plaintiffs have not moved for certification under Fed. R. Civ. P. 23(b)(2). The TAMCC and the Consolidated Order propose that each class be certified both under 23(b)(3) and (b)(2). Courts have approved such hybrid certification, and defendants offer no substantive opposition to (b)(2) certification.^{28/29} Injunctive relief is sought in Count III (p. 266), and in the Prayer for Relief at E. *See* Prayer at E (p. 299).

VII. DEFENDANTS' ATTACKS ON THE ADEQUACY OF THE PLAINTIFFS FAIL

The individual plaintiffs in this case are now mainly patients on chemotherapy, and some have died since originally being named as class representatives. Despite their circumstances, they or their estates and/or spouses produced documents and sat for depositions. Defendants'

²⁸ The Associations would be additional class representatives for the (b)(2) classes.

²⁹ *See Lemon v. Int'l Union of Operating Eng'rs Local No. 134*, 216 F.3d 577, 581-82 (7th Cir. 2000).

attacks on their adequacy and their claim that the proposed representatives “lack sufficient knowledge of their claims” and “hold views that are contrary to the fundamental premises of the complaint” are exaggerated and simply wrong.

As courts from this District have recognized, “[i]n complex actions such as this one, named plaintiffs are not required to have expert knowledge of all details of the case, ... and a great deal of reliance on the expertise of counsel is to be expected.” *In re Transkaryotic Therapies, Inc. Sec. Litig.*, 2005 U.S. Dist. Lexis 29656, at *15 (quoting *In re Lupron Mktg. & Sales Practices Litig.*, 228 F.R.D. 75, 90 (D. Mass. 2005)). As Judge Stearns explained in rebuffing an adequacy challenge similar to that made by Defendants here, “[t]here is nothing surprising in the fact that [the proposed representatives], the widows of the original class representatives, are unschooled in the intricacies of the legal process or the complexities of prescription drug pricing.” *In re Lupron*³⁰, 228 F.R.D. at 90. Similarly, the court in *County of Suffolk v. Long Island Lighting Co.*, 710 F. Supp. 1407 (E.D.N.Y. 1989), explained that “ignorance of the specifics of the action” does not render proposed representatives inadequate as long as the totality of their testimony is not “false, misleading or contradictory ... with regard to the basic issues of the case” such that “their claims [would be] subject to unique defenses [that] undermine their ability to adequately represent the class.” *Id.* at 1416.³⁰

Defendants’ attacks on plaintiffs’ knowledge of the case is misplaced as plaintiffs have demonstrated sufficient knowledge of the litigation. No such attack has been launched at UFCW. And the individual consumer representatives have similarly demonstrated sufficient knowledge. *See, e.g., Macoretta Decl.*, ¶ 2.

³⁰ *See also In re AM Int’l, Inc. Sec. Litig.*, 108 F.R.D. 190, 197 (S.D.N.Y. 1985) (citing cases); *Snider v. Upjohn Co.*, 115 F.R.D. 536, 541 (E.D. Pa. 1987) (refusing to find proposed representative inadequate in the face of defendants’ contention that the plaintiff “lack[ed] knowledge about many of the most basic matters at stake in the present case”); *Pellman v. Cinerama, Inc.*, 89 F.R.D. 386, 390 (S.D.N.Y. 1981) (noting that the proposed representative’s “unfamiliarity with particular facts is trivial in light of” their appearance as “honest and responsible individuals” and the “calibre of their counsel”).

Defendants' further claim inadequacy based on their assertion that the class representatives: (i) believed their providers prescribed AWPIDs based on their sound medical judgment; (ii) did not "understand" that their physicians benefited from increased spreads "not the drug manufacturers"; and (iii) did not believe there was any collusion between the drug manufacturers and physicians. It is not surprising that plaintiffs, being treated for serious illnesses, want to believe their doctors' exercised sound medical judgment in choosing which drug to administer. Their belief in this regard is not relevant to the proof that will establish an inflated AWP. As to their doctors benefiting from the spread, again that issue will be addressed by expert testimony and defendants' own documents, not from the testimony of the class representatives.

Finally, the fact that plaintiffs paid for drugs after the complaint was filed does not render them inadequate. The proposed class period is from January 1, 1991 "to the present." *See* CPO at ¶ 3, p. 7. Plaintiffs allege that this unlawful practice continues to the present, and in fact in many cases the published AWP and spread has increased in recent years. The individual consumer plaintiffs had no choice but to pay their percentage of the inflated cost and were unaware of the AWP Scheme when they paid for their drugs. *See, e.g.,* Haviland Decl., ¶¶ 43, 48. This hardly renders them inadequate – to the contrary it qualifies them as typical victims.

VIII. CONCLUSION

Plaintiffs respectfully request that the Court enter the CPO and that the Court (1) appoint the proffered Class 1 representatives to represent the Class 1 class; (2) certify a multi-state class for Class 2 and Class 3; and (3) appoint the proffered class representatives for Classes 2 and 3.

DATED: December 15, 2005.

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CERTIFICATE OF SERVICE

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing **PLAINTIFFS' MEMORANDUM IN SUPPORT OF PROPOSED CONSOLIDATED CLASS CERTIFICATION ORDER** to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 15, 2005, a copy to LexisNexis File & Serve for posting and notification to all parties.

By /s/ Steve W. Berman

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Exhibit A

CLASS 1 COVERAGE

Medicaid Co-Payor	
Aaronson	BMS, GSK, J&J
Shepley	J&J, AstraZeneca
Howe	AstraZeneca, GSK
Young	BMS, J&J
Clark	GSK, J&J
Hopkins	BMS
Townsend	AstraZeneca
Newell	AstraZeneca, J&J, BMS
Proposed Class 1 Dual Class Representatives	
Pipefitters	All Track 1 Defendants but Schering
UFCW	All Track 1 Defendants
BCBS of Massachusetts	Not yet a party, coverage of all Track 1 Defendants
Byrski	BMS, GSK
Barnewolt	J&J
Barreca	J&J, BMS, GSK
Cauble	BMS
Choice	BMS, GSK
Dison	BMS
Garcia	BMS, Schering
Kendall	GSK, BMS, J&J
Leef	BMS
G. Miller	BMS
Nelson	BMS, GSK
Palenica	BMS, GSK
Tell	GSK, BMS
Vernick	BMS
Vescovi	BMS, J&J
Weaver-Zech	J&J
Wessels	AstraZeneca
J. Miller	GSK
Shoemaker	BMS
Vanderwal	J&J
Hopkins	BMS
Thompson	AstraZeneca

CLASS 2 - IF MULTISTATE CLASS

UFCW	All Track 1 Defendants
PMBT	All Track 1 Defendants but Schering
Sheet Metal Workers	All Track 1 Defendants but Schering

CLASS 2 - IF MASSACHUSETTS CLASS ONLY

Pipefitters	All Track 1 Defendants but Schering
BCBS of Massachusetts	All Track 1 Defendants

CLASS 3 - REPRESENTATION IF MULTISTATE

UFCW	AstraZeneca, BMS, GSK, Schering
Carpenters Fund	AstraZeneca, GSK, Schering
Teamsters of Philidelphia	AstraZeneca, BMS, GSK, J&J, Schering
Man-U Service	GSK, Schering
Twin Cities	AstraZeneca, GSK, Schering
Sheet Metal Workers	Records to be produced
The Individual Consumers Listed in the CPO	Collectively all Track 1 Defendants

CLASS 3 - IF MASSACHUSETTS CLASS ONLY

Pipefitters	All Track 1 Defendants but Schering
BCBS of Massachusetts	All Track 1 Defendants

23(B)(2) REPRESENTATIVES

Vermont Public Interest Group
Wisconsin Citizen Action
New York Statewide Senior Action Council
Citizen Action of New York
Citizens for Consumer Justice

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:) MDL No. 1456 and
AVERAGE WHOLESALE PRICE) C.A. No 01-12257-PBS
PHARMACEUTICAL LITIGATION) Courtroom No. 19
) 1 Courthouse Way
Boston, MA 02210

FEBRUARY 10, 2005

2:10 P.M.

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

Valerie A. O'Hara
Official Court Reporter

1 that there's been a cross-subsidization going on. It's been
2 recognized that they're not paying enough on the
3 administration side and they're overpaying on the drug side,
4 and how that happens is a function of the overall, the
5 relative market power of the different groups.

6 Anthem in Maine, there's a document we cite in our
7 brief, your Honor, Anthem of Maine is an internal document
8 where they're talking about a particular oncology group that
9 has enormous power in that state.

10 They say we don't have much bargaining power with
11 them. I then take the deposition of someone from Anthem of
12 Virginia, which has a 65 percent market share, and they say
13 we have a fair amount of market power here. We dictate the
14 fee schedule, but we negotiate with particular oncology
15 groups, particular physician groups, depending upon their
16 relative power in that area.

17 It's the same type of bargaining that you see,
18 individualized bargaining, that you see going on on the PVM
19 side. It's really no different. It's each payor.

20 THE COURT: I understand. I take it you're not
21 making this argument for the Medicaid Part B beneficiaries
22 where the Government reimburses?

23 MR. CAVANAUGH: No, your Honor. With respect to
24 Medicaid Part B, Ms. Birnbaum will address the variations in
25 state law that make it inappropriate to certify a class, a